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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,121	10/20/2000	Jeffrey Schlom	45394	7805

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EXAMINER
YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/693,121	SCHLOM ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-20,22,24-31 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *17-20,22,24-31 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Re: Schlom *et al*

1. The amendment filed 12/30/2005 is acknowledged and entered into the record. Accordingly, claims 1-16,21,23, and 32-33 are canceled without prejudice or disclaimer, and claim 36 is newly added.

2. Claims 17-20,22,24-31, and 35-36 are pending. It is noted that claim 34 was previously withdrawn because it was dependent on a claim that was withdrawn as being drawn to non-elected embodiments. It has now been amended to depend on an examined and elected invention and therefore examined on the merits.

3. Claims 17-20,22,24-31, and 34-36 are examined on the merits.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 102

5. The rejection of claims 17-19,24-26,28, and 35 under 35 USC § 102(e) as being anticipated by Spitler *et al* (US Patent 5,925,362) is maintained for the reasons of record. Applicant argues the cited US Patent does not anticipate the claims of the instant invention. Specifically, applicant argues that each claim has not been examined on own merits in comparison with the reference. Applicant contends that claims 18 and 35 require the administration of "co-stimulatory molecules" along with the PSA or CTL eliciting epitope thereof, of which applicant allege Spitler *et al* does not disclose.

Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). In the instant case, given the fact that the specification has not specifically defined the term "co-stimulatory molecule" and given the broadest reasonable interpretation of the term, a cytokine is encompassed by a "co-stimulatory molecule". Therefore, Spitler *et al* do teach a method of administering PSA or a CTL eliciting epitope thereof in combination with a co-stimulatory molecule (i.e. a cytokine). It is also noted that applicant has only recently amended the claims to recite the combination of PSA with a co-stimulatory molecule. Previously, the claims were drawn to a method comprising the administration of PSA with a cytokine or a co-stimulatory molecule. Therefore each and every limitation of the claims has been anticipated by Spitler *et al*.

Applicant also argues that claims 30 31, and 34 also discuss prime boost regimes, of which applicant argues Spitler *et al* does not disclose. However, claims 30,31 and 34 are not included in the rejection under 35 USC 102(e). Thus applicant's arguments are not deemed persuasive.

Applicant also argues that the claims require that the immune reaction generated must be a CTL eliciting immune response. Applicant concludes by indicating that the response generated by Spitler *et al* "only talks about any immune response be it

proliferative response or antibody immune response." Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. In the instant case, applicant only states that the response generated by Spitler *et al* is not a CTL generating response. Applicants have not set forth any objective evidence to indicate that such a response has not been generated. Moreover, contrary to applicant's assertions, Spitler *et al* does in fact indicate that a "cellular immune response" (see col. 7, lines 56-60, for example) to PSA may be generated. In addition, the claim only recites a "cytotoxic T-cell eliciting immune response", which does not require an exclusive CTL only type response. Since the office does not have the facilities and resources to provide the factual evidence needed in order to establish that the PSA and cytokines/co-stimulatory molecules administered in the method by Spitler *et al* is any different from that being claimed, in the absence of evidence to the contray, the burden is on the applicant to prove that the response generated is different from the claimed. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Finally, applicant attempts to overcome the rejection by submitting a declaration filed under 37 CFR § 1.131 by Dr. Schlom, indicating that prior to the filing date of Spitler *et al*, Applicant conceived the idea of administering to a host an effective amount

of PSA specifically using a pox viral vector encoding PSA to elicit an immune response. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The declaration filed on 12/01/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the 102(e) reference of record. The claims of the instant invention are drawn to a method of generating a CTL eliciting immune response comprising the administration of a PSA or a CTL eliciting epitope thereof. The declaration filed by Dr. Schlom provides evidence that they were in possession of a method of administering a vector comprising a sequence that encodes PSA (see points 3 and 10 of the declaration filed 12/01/2005, for example). The scope of the declaration is not commensurate with the scope of the claims, because the claims of the instant invention are drawn to a method of administering a peptide, while the declaration is drawn solely to a method of administering a vector/DNA molecule.

Moreover, the cited reference is a U.S. patent that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718. When the reference in question is a noncommonly owned U.S. patent or patent application publication claiming

the same invention as applicant and its publication date is less than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, must be by way of 37 CFR 41.202 instead of 37 CFR 1.131.

Therefore, the rejection of claims under 35 USC 102 as being anticipated is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 103

6. The rejection of claims 17-20,22,24-31, 35, and now newly amended and added claims 34 and 36 under 35 USC § 103(a) is maintained for the reasons of record. Applicant argues that the claims of the instant invention are not obvious over the cited prior art. Specifically applicant argues that the declaration by Dr. Schlom (filed 12/01/2005) overcomes the Spitler *et al* reference as prior art. Applicant further contends neither Spitler *et al* nor the declaration by Dr. Schlom show any human treatment data. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The declaration by Dr. Schlom filed on 12/01/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Spitler *et al* reference for the reasons presented above (see paragraph 5 above). With regard to the arguments concerning "human treatment data" applicant is essentially questioning the enablement of the issued US Patent. However, all US patents are presumed valid and enabling, and therefore the examiner will not comment on the validity of any issued US Patent. It is also noted that applicant has amended the claims to recite the administration to a

human host. Spitler et al also encompass this limitation because they indicate that the host can also encompass humans (see col. 7, line 45, for example, and col. 2, lines 55-56, wherein they specifically distinguish between pharmaceutical and "veterinary" vaccines).

Applicant additionally argues that the examiner used impermissible hindsight to reconstruct the instantly claimed invention by essentially "picking and choosing various elements" to render obvious the instant invention. Specifically, applicant argues that the combination reference do not specifically suggest the use of co-stimulatory molecules or suggest the use of "a heterologous prime boost". Applicant submits evidence in the form of an abstract (i.e. 2002 ASCO Meeting) and Press Release to substantiate the claims of "surprising" results of using a prime boost of pox virus expressing PSA. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The evidence relied upon should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992), Ex parte C, 27 USPQ2d 1492 (Bd. Pat. App. & Inter. 1992); In re Nolan, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977) and In re Eli Lilly, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) as discussed in MPEP § 716.02(c). Moreover, evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Whether the unexpected results

are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980).

In the instant case, applicant has not clearly established that the differences in results are in fact unexpected or unobvious to one of ordinary skill. Applicant have essentially submitted conclusive remarks, without specifically indicating why one of skill in the art would find the use of heterologous prime boosting to be unobvious over the prior art. Moreover, the evidence proffered is not commensurate in scope to the claims of the invention. Specifically, the evidence submitted teaches the administration of a viral vectors encoding PSA followed by subsequent "heterologous prime boost" using viral vectors. However, the claims of the instant invention are drawn to the initial administration of PSA or CTL eliciting epitopes thereof, which are proteins or polypeptides, and not nucleic acdis or viral vectors as provided in the evidenced submitted. Thus, the evidence submitted is not commensurate in scope.

In addition, "[a]ny judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge, which was within the level of ordinary skill in the art at the time the claimed invention, was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). In the instant case, Spitler *et al* taught the use of

administering viral expression vectors such as vaccinia and other pox viruses (see col. 8, lines 5-15, for example), while Fields and Hodges *et al* provided for the different types of pox viruses, such as avipox, and the use of specific "co-stimulaotry" molecules, such as B7-1 or B7-2, respectively. Spitler *et al* provided sufficient motivation and reasonable expectation of success to use PSA in combination with pox viral vectors as "prime boost" because they indicated that "booster inoculations" may be given (see col 9, lines 5-6, for example) and that "alternate protocols" may be advantageous (see col. 9 for example).

Therefore, the rejection of claims under 35 USC 103(a) as being obvious as a whole over the cited references is maintained for the reasons of record.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen, Examiner
Art Unit 1643
March 15, 2006

CHRISTOPHER YAEN
PATENT EXAMINER